an unpredictable amount of experimentation required to use the claimed invention". As support, the Office Action states that the "prior art does not predict a way to use the claimed combination of genes", citing Vispe, Biochimie, 79:587-592 (1997) (Vispe). Applicants respectfully traverse.

The Utility Guidelines are applicable to rejections both for lack of utility under 35 U.S.C. § 101 and for failing to teach "how to use" under 35 U.S.C. § 112, first paragraph (see, page 296, left column, lines 30-35 and page 300, right column of the Guidelines). Therefore, the Utility Guidelines will be used to determine that the present application discloses to the skilled artisan how one would "use a Rad51 gene combined with a tumor suppressor gene".

The Utility Guidelines indicate that a rejection is proper only in the "rare instance" where an assertion made by the applicant as to how to use the invention is not credible to one of ordinary skill in the art (pages 296-298 of the Guidelines).

Regarding the qualifications for "credibility", the guidelines indicate that a specific assertion of how to use the invention not only creates a presumption of validity, but also is deemed credible "unless (a) the logic underlying the assertion is seriously flawed, or (b) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion" (page 303 of the guidelines, emphasis supplied).

Moreover, only one use need be asserted in order to meet the utility or "how to use" requirement.

One example of how the skilled artisan would use the claimed invention is for the production of a Rad51 protein and a tumor suppressor protein. These two proteins could then be used in a variety of applications including but not limited to the competitive binding assays to identify agents which bind to Rad51, as described on page 23, lines 9-20 of the application and for the generation of antibodies (see page 34, line 21). Furthermore, the nucleic acids can be used to determine co-expression patterns, etc.

Certainly the above stated uses meet the standard of being credible. The logic is not seriously flawed, nor is the assertion based on inconsistent logic. Applicants submit that the skilled artisan would routinely be able to apply the claimed composition

comprising a nucleic acid encoding a Rad51 protein and a nucleic acid encoding a tumor suppressor protein to at least one use.

Regarding Vispe, the Office Action states that Vispe "does not show use of a combination of a Rad51 gene and a tumor suppressor gene". Applicants submit that Vispe does not contradict the assertions in the application, rather, Vispe supports the novelty of the claimed subject matter.

Furthermore, regarding the In re Wands factors listed in the Office Action, Applicants submit that the present invention meets this criteria for enablement. Specifically, the nucleic acids encoding Rad51 protein and tumor suppressor genes are known in the art. The skilled artisan could routinely combine these nucleic acids as described in the application to practice the claimed invention. This would not take an undue quantity of experimentation. Applicants, therefore, submit that provided with the present application the skilled artisan could make and use the claimed invention and request that the rejection be withdrawn.

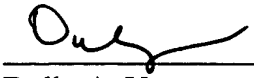
The Rejections Under 35 U.S.C. Section 112, Second Paragraph

Claims 41-44 are rejected under 35 U.S.C. Section 112, second paragraph, as "indefinite" for having improper antecedent basis. Applicants have amended the claims to have proper antecedent basis, and therefore request that the rejection be withdrawn.

Applicants submit that all the claims are in condition for allowance and an early notification of such is solicited.

Respectfully submitted,

FLEHR HOHBACH TEST
ALBRITTON HERBERT, LLP



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APPENDIX:

40. A composition comprising:

a) nucleic acid encoding a Rad51 protein; and

b) nucleic acid encoding a tumor suppressor protein.

42. (Amended) A composition according to claim [38] 40 wherein said tumor suppressor protein is BRCA1.

43. (Amended) A composition according to claim [38] 40 wherein said tumor suppressor protein is BRCA2.

44. (Amended) A composition according to claim [38] 40 comprising:

a) nucleic acid encoding a Rad51 protein;

b) nucleic acid encoding a BRCA1 protein;

c) nucleic acid encoding a BRCA2 protein; and

d) nucleic acid encoding a p53 protein.